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09/889,251	11/01/2001	Robert K. Naviaux	UCSD1140-1	9760

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[REDACTED] EXAMINER

SPIVACK, PHYLLIS G

ART UNIT	PAPER NUMBER
1614	21

DATE MAILED: 08/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. <b>09/889,251</b>	Applicant <b>Naviaux</b>
Examiner <b>Phyllis G. Spivack</b>	Art Unit <b>1614</b>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.138 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on Apr 8, 2003

2a)  This action is FINAL. 2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 1-6, 8-27, 29-46, 54-57, 62, and 66 is/are pending in the application.

4a) Of the above, claim(s) 29-46, 54-57, and 62 is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-6, 8-27, and 66 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some\* c)  None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

1)  Notice of References Cited (PTO-892)

4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

5)  Notice of Informal Patent Application (PTO-152)

3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). 18

6)  Other: \_\_\_\_\_

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Applicant's Amendment filed April 8, 2003, Paper No. 15, is acknowledged. Claims 7 and 28 are canceled. Claims 47-53, 58-61 and 63-65 were canceled in Paper No. 10. Claims 29-46, 54-57 and 62 were previously withdrawn from consideration by the Examiner as being drawn to inventions that are independent or distinct from the invention originally claimed. Accordingly, claims 1-6, 8-27 and 66 remain under consideration.

An Information Disclosure Statement filed January 15, 2002, Paper No. 18, is further acknowledged and has been reviewed to the extent each is a proper citation on a U.S. Patent.

Two Declarations filed by Dr. Naviaux under 37 C FR 1.132 on April 8 and 16, 2003, Paper Nos. 16 and 17, are further acknowledged.

In the last Office Action claims 4 and 5 were rejected under 35 U.S.C. 112, both first and second paragraphs, as being indefinite with respect to the recited "carbonyl derivatives" and as lacking a clear written description to enable any person skilled in the art to make and use the invention.

Subsequent to the amendment to claims 4 and 5 wherein "derivative" is deleted and replaced with the term "moiety", the rejections of record are withdrawn.

All claims were rejected in the last Office Action under 35 U.S.C. 112, first paragraph, as lacking adequate enablement with respect to the breadth of the claims for treating mitochondrial disorders.

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In view of the Naviaux Declarations, wherein support has been provided for certain specific disorders that are genetic defects in mitochondrial or nuclear DNA, and amendments to claims 1 and 25, this rejection of record is withdrawn.

There were four rejections that were either maintained or set forth under 35 U.S.C. 102 in the last Office Action. Claims 1, 7, 25 and 27 were rejected under 35 U.S.C. 102(b) as being anticipated by Isono et al., JP 53056690; claims 1-7 and 25-27 were rejected under 35 U.S.C. 102(e) as being anticipated by von Borstel et al., U.S. Patent 6,258,795; claims 1-28 and 66 were rejected under 35 U.S.C. 102(a) as being anticipated by Naviaux et al., "Mitochondrial Dysfunction in Human Pathology" meeting; and claims 1-28 and 66 were rejected under 35 U.S.C. 102(e) as being anticipated by von Borstel et al., U.S. Patent 6,472,378.

Applicant collectively argues that none of the four references describes methods for treating the specific disorders set forth in claim 1.

Isono teaches the administration of N-acetyl-2',3',5'-triacetate cytidine, a compound of formula I, to treat a hormone imbalance. Primary lactic acidosis may occur in association with diabetes mellitus, a disease characterized by a hormone imbalance, wherein the hormone is insulin.

Von Borstel (Patent 6,258,795) teaches the administration of compounds of formula II and formula III to treat a variety of disorders or symptoms associated with those disorders that relate to cardiac insufficiency, myocardial infarction, liver disease or damage, muscle performance, lungs, diabetes, central nervous system, cerebrovascular disorders and senile

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dementias. These disorders encompass or characterize the recited conditions of instant claims 1 and 25.

The Naviaux document is specifically directed to the treatment of renal tubular acidosis, lactic acidemia, encephalopathy, Leigh syndrome, pyruvate dehydrogenase (PDH) deficiency, Complex I deficiency and Complex IV (COX) deficiency comprising administering triacetyluridine.

Von Borstel (Patent 6,472,378) teaches the administration of acyl derivatives of uridine and cytidine, including 2',3',5'-tri-O-acetyluridine, to treat various mitochondrial disorders. See, in particular, column 12.

Accordingly, treating the disorders recited in claims 1 and 25, and reducing the symptoms associated with these disorders, are taught in the prior art.

The four rejections of record under 35 U.S.C. 102 are maintained for the reasons of record.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

In Paper No. 10, the definition of  $R_1$  was amended to include the additional option of "O" in claims 1 and 25 which was not recited in the original claims and does not find support in the specification.

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No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C FR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C FR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this Final Action.

Any inquiry concerning this communication should be directed to Phyllis Spivack at telephone number 703-308-4703.

August 2, 2003



PHYLIS SPIVACK  
PRIMARY EXAMINER